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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

GEN-PROBE INCORPORATED,
Plaintiff and Counterdefendant

v.

BECTON, DICKINSON AND COMPANY,
Defendant and Counterclaimant

AND RELATED COUNTERCLAIMS

Case No. 09cv2319 BEN (NLS)
Case No. 10cv0602 BEN (NLS)

**JOINT MOTION FOR DETERMINATION OF
DISCOVERY DISPUTE (FOURTH DISPUTE)**

DISCOVERY MATTER

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Pursuant to the Amended Scheduling Order issued by Magistrate Judge Nita L. Stormes on July 1, 2010 (Docket No. 52), Defendant Becton, Dickinson and Company ("BD") and Plaintiff Gen-Probe Incorporated ("Gen-Probe") hereby jointly move the Court for determination of a discovery dispute arising from Gen-Probe's Responses to BD's First Set of Requests for Production of Documents. Because of the number of responses in dispute, each of Sections I - XI below includes a representative request and response.¹ A complete copy of Gen-Probe's responses to BD's requests for production is attached to the Declaration of Brian Carroll as Exhibit A. Counsel for both parties hereby declare they have met-and-conferred in an effort to resolve or narrow these disputes, including during lengthy telephone conferences on June 30, 2010 and again on July 8, 2010.

Joint Request to Exceed the Court's 10-Page Limit

Because of the number of disputes addressed below, the parties' respective submissions (BD's statement and reply, collectively, and Gen-Probe's opposition) each exceed the 10-page limit specified in this Court's order by approximately 2 and ½ pages. The parties' hereby jointly request leave to submit this joint brief including approximately 5 total additional pages of argument and support.

¹ As set forth in greater particularity below, Gen-Probe objects to and disputes BD's selections of "a representative request[s] and response[s]" as, in fact, "representative" for all the parties' disputes addressed herein. Rather, Gen-Probe submits that the Court should not grant BD's motion without assessing the merits of BD's arguments as applied to each of the requests for which BD only sets forth such a "representative request and response" of its own choosing.

BD responds that it would be overly burdensome to the Court, and unnecessarily so, for BD to have addressed individually each of Gen-Probe's repetitive objections to the 76 requests in dispute. It would also be impossible to address each request in substance within the reasonable page limits specified in this Court's order. Gen-Probe should not be rewarded for generating so many disputes that the briefing becomes unwieldy or impossible. In fact, other than Request No. 72 (included in Section II), which is nearly identical in form to Request No. 25 (addressed expressly in Section I), Gen-Probe does not contend that any of the requests identified by BD as "representative" fail to be representative of the additional requests in dispute. Should the Court require separate briefing as to any additional requests in dispute, BD is prepared to provide a supplemental submission in support of its motion.

I. Gen-Probe's Refusal to Produce Documents Concerning Commercial Embodiments of the Claimed Process Patent Invention(s).

Request No. 25:² All documents concerning the testing, manufacture, use, sale or offer for sale of the TIGRIS Instrument, including all engineering notebooks, notes, memoranda, correspondence, emails, prototypes, engineering change orders, bills of material, research reports, development proposals, project approvals, project summaries, new product disclosures or proposals, drawings, sketches, schematics, models, computer models, simulations, manufacturing specifications or protocols, testing specifications or protocols, technical manuals, product manuals, service manuals, operation manuals, samples, presentations, data files, meeting minutes, diaries, calendars, publications, product specifications, product development documents, theory of operation documents, failure modes and effects documents, and any other design and technical documents.

Response: Gen-Probe *will produce the design history file for the TIGRIS Instrument and non-privileged and responsive documents from the project file for the TIGRIS Instrument* in its possession, custody, or control that can be identified after a reasonable search, to the extent such documents have not already been produced.

Gen-Probe's response to this Request is made subject to and without waiver of the following Objections: Gen-Probe incorporates each of the foregoing General Objections into its response. Gen-Probe further objects to this Request on the grounds that it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. *Documents responsive to this request that concern Gen-Probe's commercial embodiments of the Process Patents and were created after the effective filing date of those patents are irrelevant.* See e.g., *Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1291-92 (D. Del. 1987); *Singh v. Brake*, 317 F.3d 1334, 1345 (Fed. Cir. 2002). Gen-Probe further objects to this Request on grounds that the burden or expense of the proposed discovery outweighs its likely benefit. This Request would encompass essentially any document in the entire company that references TIGRIS. Gen-Probe also objects to this Request on grounds that it calls for production of information protected by the attorney-client privilege, the work product doctrine, and/or other privileges and immunities. (Emphases added).

A. BD's Statement of Reasons to Compel Discovery:

In response to BD's Request No. 25 and similar requests seeking documents concerning the TIGRIS instrument, Gen-Probe's commercial embodiment of the five asserted "Process Patents," Gen-Probe agreed to produce responsive documents (1) in the TIGRIS "Design History File" and "Project File" and (2) documents outside those files (e.g., individual employees' files, other shared files, email, lab notebooks, etc.) created "*before the effective*

² Gen-Probe's objection and response to Request No. 25 is representative of other responses in which Gen-Probe purports to limit its responses to the TIGRIS "Design History File" and "Project File" and/or to documents created before "the effective filing date" of the Automation Patents. These requests include Request Nos. 21, 22, 26, 29, 31-37, 39, 128-129, and 196.

1 **filing date**” of the Process Patents, which Gen-Probe contends is May 1, 1998.³ Gen-Probe is
 2 improperly withholding highly relevant documents, from May 1998 through the present, not
 3 typically retained in the “Design History” and “Project” files.⁴

4 BD expects Gen-Probe’s documents to show that Gen-Probe did not possess and did not
 5 enable the alleged invention(s) as broadly as claimed in the asserted patents, rendering the
 6 patents invalid. *See* 35 U.S.C. § 112; *see also Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247,
 7 1260-1261 (Fed. Cir. 2004) (evidence of absence of commercial embodiment is relevant to
 8 enablement); *The Johns Hopkins University v. CellPro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir.
 9 1998) (considering laboratory’s experimental failures after the effective filing date for
 10 enablement).⁵ Between May 1, 1998 and the 2004 launch of TIGRIS, Gen-Probe encountered
 11 substantial difficulty completing its alleged invention and bringing the product to market, as
 12 described in its 2002 10K filing:

13
 14 Our ability to meet demand for increased automation in the blood
 15 screening and diagnostic markets depends on our ability to develop our
 16 TIGRIS instrument. ***This product, which incorporates sophisticated
 hardware and software, may not perform as anticipated, and there may
 be unforeseen delays in its final release.*** . . . During 2001, we terminated
 17 our relationship with RELA, Inc., the original outside contractor for the
 18 design and development of this product and entered into a relationship
 19 with KMC Systems, Inc. for its completion. Carroll Decl. at Ex. B
 (emphasis added).

20 The requested documents concerning Gen-Probe’s post-filing experimentation are
 21 relevant to the “underlying factual inquiries” of whether the specifications in the patents teach
 22 those skilled in the art to how to make and use the full scope of the claimed invention without
 23 “undue experimentation.” *See Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, (Fed. Cir.

24 ³ The “effective filing date” has not yet been established in this case.

25 ⁴ Examples of such documents include e-mail; correspondence; memoranda; meeting notes and
 26 agendas; lab and engineering notebooks; invention disclosure documents; research reports;
 presentations; and drafts or non-final documents contained in individuals’ files.

27 ⁵ The two cases cited by Gen-Probe in support of its limited response are inapposite. *Singh v.*
 28 *Brake* does not address whether documents created “after the effective filing date” of an asserted
 patent are discoverable. *Phillips v. U.S. Steel* stated, *in dicta*, only that “developments in the art”
 as a whole after a patent’s effective filing date are not relevant to the issue of enablement.

1 1997).⁶ Gen-Probe's refusal to produce its internal documents (or documents created by RELA's
 2 successor KMC) is inconsistent, inexplicable and unjustifiable.⁷ For these reasons, BD requests
 3 that the Court overrule Gen-Probe's objections to Request Nos. 21, 22, 26, 29, 31-37, 39, 128-
 4 129, and 196 and order Gen-Probe to produce responsive documents including those *outside* the
 5 TIGRIS "Design History" and "Project" files from May 1, 1998 through the present.

6
 7 **B. Gen-Probe's Statement of Reasons for Objecting to Discovery:**

8 This dispute is typical of nearly all the disputes addressed in this motion in two important
 9 ways. First, BD's requests for "all documents" of virtually every type, unbound by time and
 10 untethered to any claim or defense in this action, are facially overbroad. *See, e.g.,*
 11 *DaimlerChrysler AG v. Fueling Advanced Techs., Inc.*, (S.D. Cal. 2003), Case No. 3:00-cv-
 12 01541, Dkt. No. 192, at 5. Second, Gen-Probe has supplied a candid disclosure of the category
 13 of documents for which it will conduct a reasonable search in response to BD's requests, despite
 14 their over-breadth, and limited or complete lack of relevance. Unfortunately, no matter what
 15 reasonable approach Gen-Probe has articulated, BD has stubbornly insisted that "all documents"
 16 must be searched and produced, declining even to wait until it receives Gen-Probe's full proffer
 17 of documents before determining if there is even an arguable basis for asking for more.

18 Here, with respect to its discovery of "all documents concerning" Gen-Probe's TIGRIS
 19 Instrument, Gen-Probe's sole commercial embodiment of the asserted Automation Patents, BD is
 20 wrong on both the law and the facts:

21 ///

22 ///

23 ///

24 ///

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26

27 ⁶ The requested documents also bear directly on secondary consideration arguments.

28 ⁷ Gen-Probe agreed to produce documents concerning all TIGRIS design and development work,
 including documents created *after* "the effective filing date," that were created by RELA, Inc.

1. **BD is wrong on the law – “all documents” on Gen-Probe’s embodiment of the Automation Patents post-dating their effective filing date are irrelevant to any of BD’s defenses**

BD argues that “all documents” concerning TIGRIS are relevant to support BD’s enablement defense under 35 U.S.C. § 112 as a rebuttal to Gen-Probe’s infringement claims.⁸ BD overreaches. *Gen-Probe’s TIGRIS instrument is not on trial in this case.* To establish invalidity under § 112, BD must show that one of ordinary skill could not make and use the *claims* of the Automation Patents based on their *specification* combined with knowledge in the field *at the time that specification was filed with the PTO.* *Singh v. Brake*, 317 F.3d 1334, 1345 (Fed. Cir. 2002). Although BD asserts that the “effective filing date” has not been determined, BD does not dispute that all of the Automation Patents have a common specification that was submitted in a non-provisional application to the PTO on April 30, 1999. This is the *latest* arguable “effective filing date” for those patents.⁹ Thus, Gen-Probe’s “post-filing” development work on the TIGRIS embodiment of the Automation Patents is irrelevant to BD’s defense.

BD’s reliance on *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247 (Fed. Cir. 2004) to argue the contrary is misplaced. In *Chiron*, the question was whether certain alleged “nascent technology” embraced by a patent claim was enabled by the patent’s specification under 35 U.S.C. § 112. The Federal Circuit held that the *absence* of a commercial embodiment employing that nascent technology was relevant to the determination of that question. *Id.* at 1260-61. Here, by contrast, BD does not dispute that TIGRIS *is* a commercial embodiment of the Automation Patents, and in any event, as set forth below, Gen-Probe will produce the documents BD will need to confirm or challenge that position. (*See, e.g.,* Long Decl. ¶¶ 3(a)-(c), (f)-(h).)

⁸ BD also argues, without support, that “all documents” concerning TIGRIS “bear directly on secondary consideration arguments.” (*Supra*, n. 6.) As Gen-Probe sets forth below and in opposition to BD’s arguments seeking contentions and evidence of secondary considerations in the Joint Motion For Determination Of Discovery Dispute (Third Dispute), Dkt. No. 56, in connection with BD’s stated interrogatory numbers 2 and 3, that contention misconstrues the nature of “secondary considerations” and, at a minimum, is premature at this stage of the case.

⁹ The original patent application giving rise to each of the Automation Patents was filed on April 30, 1999. That original application further claims priority to a “provisional” application filed on May 1, 1998 that has all the same material disclosure as set forth in the specification of the original application. Thus, the “effective filing date” of the Automation Patents is May 1, 1998 at the earliest, and April 30, 1999 at the latest.

1 Similarly, *The Johns Hopkins University v. CellPro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998),
 2 does not support BD's arguments. Contrary to those arguments, the *CellPro* court found that the
 3 alleged "evidence" of failed attempts to reproduce an invention after the patent filing date *did not*
 4 support the defendant's enablement defense because there was no showing that those attempts
 5 followed *the patent's disclosure*. *Id.* at 1360-61. Here, BD does not claim that TIGRIS, first
 6 approved for use by the FDA in December 2003, (Kacian Decl. ¶ 7), was such a "failure."

7 Although BD criticizes Gen-Probe's reliance on *Phillips Petroleum Co. v. U.S. Steel*
 8 *Corp.*, 673 F. Supp. 1278 (D. Del. 1987), and *Singh v. Brake*, 317 F.3d 1334 (Fed. Cir. 2002),
 9 those cases are directly on point. *Phillips* expressly holds that "post-filing developments in the
 10 art are irrelevant to the enablement inquiry." 673 F. Supp. at 1291 (citing *W.L. Gore &*
 11 *Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1556 (Fed. Cir. 1983), *cert. denied*, 469 U.S.
 12 851 (1984)). "The critical inquiry" is not what the patentee discovers after the filing date, but
 13 "whether, at the time the application was filed, the application contained a description sufficient
 14 to enable one skilled in the art to practice the invention." *Id.* at 1291-92. *Singh* confirms that
 15 enablement "does not depend on what [the inventor] knew, but rather on whether the *application*
 16 enables one skilled in the art to make and use the invention *at the time the patent application was*
 17 *filed.*" 317 F.3d at 1345 (italics added); *see also* BD's own cited case, *Genentech, Inc. v. Novo*
 18 *Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) ("The question before us is whether the
 19 specification would have enabled a person having ordinary skill in the art *at the time of filing.*")

20
 21 2. **BD is wrong on the facts – the documents that Gen-Probe has agreed to**
 22 **search through and produce contain all the documents BD could need**

23 Notwithstanding BD's erroneous assertion of the relevance of "all documents"
 24 concerning TIGRIS, Gen-Probe has stated its intention to produce hundreds of thousands of
 25 pages of documents directly responsive to BD's Request No. 25 and other requests. As set forth
 26 in the accompanying declarations of Tina Ninteman, Daniel L. Kacian, R. William Bowen, and
 27 Alexander E. Long, these documents comprise all the documents *dating up to and past the*
 28 *launch of that product in late 2003 through to the present* that BD can argue are possibly

relevant to its defenses concerning Gen-Probe's TIGRIS embodiment of the Automation Patents, including: (1) the TIGRIS design history file and project file, (Ninteman Decl. ¶¶ 2-4; Long Decl. ¶ 3(c)); (2) Gen-Probe's entire production of documents in the arbitration proceeding of *Gen-Probe Incorporated v. Bayer Corporation and Bayer Healthcare LLC*, JAMS Ref. No. 1240015058 and JAMS Ref. No. 1100045987, (Bowen Decl. ¶ 2; Long Decl. ¶ 3(g)); (3) all documents Gen-Probe received from RELA, Inc., the former employer of the inventors of the Automation Patents, (Ninteman Decl. ¶ 5; Bowen Decl. ¶ 3; Long Decl. ¶ 3(b)); (4) all documents relating to the conception, reduction to practice, research, development, or manufacture of the inventions of the asserted patents, including embodiments thereof, created on or before the April 30, 1999 – the latest arguable “effective filing date” for the Automation Patents – which includes, among other things, “engineering notebooks, notes, memoranda, correspondence, emails, prototypes,” etc. concerning the TIGRIS instrument, (Ex. A, Request No. 1, at 4-5; Long Decl. ¶ 3(a)); and (5) its entire FDA submission for the TIGRIS Instrument for inspection and copying, (Long Decl. ¶ 3(f); Bowen Decl. ¶ 6).

In view of the lack of relevance of *any* documents concerning Gen-Probe's TIGRIS instrument post-dating April 30, 1999 to support BD's enablement defense, Gen-Probe's proffered production is more than reasonable.

C. BD's Reply to Gen-Probe's Statement of Reasons:

As an initial matter, Gen-Probe's objections (repeated in nearly every section) that BD requires production of “all” documents are disingenuous. As BD explained during the meet-and-confer, BD is not seeking production of “all” documents responsive to any requests. BD requests only that Gen-Probe undertake reasonable searches consistent with its obligations under the Federal Rules.¹⁰ In any event, Gen-Probe's objections that BD's requests seek “all” documents

¹⁰ With respect to ESI, the parties have been ordered to agree separately as to the search protocols to be followed. That process, however, is distinct from Gen-Probe's obligations to respond to written discovery. For example, even if Gen-Probe agrees to make broad ESI searches, it could still withhold responsive documents identified in such searches based on its narrow written responses to discovery requests. The ESI agreements also will not address Gen-Probe's hard-copy document collection.

do not provide a basis for Gen-Probe's refusal to search for responsive documents. Indeed, 44 of the 66 requests that Gen-Probe served on BD in this case seek "all" responsive documents.

In response to the specific requests addressed in this section, a reasonable search must at least include the types of documents specified above, in footnote 4, created after April 1999¹¹ that may be located outside the "official" TIGRIS design files. Contrary to Gen-Probe's arguments, Gen-Probe put the design and development of its TIGRIS instrument at issue when it accused BD of infringing patents directed to the TIGRIS design. Notably, Gen-Probe has not identified any specific undue burden imposed by BD's requests. Blankenship v. Hearst Corp., 519 F.2d 418, 429 (9th Cir.1975) ("The party resisting discovery must explain why the discovery is impermissible and has the burden to clarify, explain and support its objections.").

Gen-Probe cannot argue in good faith the requested documents concerning commercial embodiments of the asserted patents after the patent filing date -- including documentation of problems Gen-Probe had in producing a working embodiment of the claimed invention -- are not relevant. In another patent case, Mr. Swinton on behalf of Gen-Probe successfully argued that "documents reflecting the . . . *actual* reduction to practice of the inventions . . . *after* the alleged priority date would be highly relevant . . . [and] would be powerful evidence that the claimed inventions . . . are invalid for lack of enablement." (emphasis original). See Carroll Decl., Ex. C; see also Single Chip Systems Corp. v. Intermec IP Corp., 2006 WL 4660129, *19 (S.D. Cal. 2006) (commercial embodiments relevant to secondary considerations); Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F.Supp. 1116 (S.D.N.Y. 1970) (commercial embodiments relevant to reasonable royalty calculation); Dr. Systems, Inc. v. Fujifilm Medical Systems USA, Inc. 2008 WL 1734241, *2 (S.D. Cal. 2008) (Stormes, M.J.) ("The scope of discovery in patent cases "should be liberally construed").

¹¹ April 1999 is still 3 ½ years earlier than the earliest *actual* filing date of any asserted Process Patent.

1 **II. Gen-Probe's Refusal to Produce Documents Concerning Commercial Embodiments**
 2 **of the Claimed Penetrable Cap Patent Inventions**

3 **Request No. 67:** ¹² Any project files relating to the design or development of Gen-Probe's
 4 Penetrable Caps or any prototype thereof.

5 **Response:** Gen-Probe will produce non-privileged and responsive documents *for representative*
 6 *assays* that include the Penetrable Cap in its possession, custody, or control that can be identified
 after a reasonable search to the extent any exist.

7 Gen-Probe's response to this Request is made subject to and without waiver of the following
 8 Objections: Gen-Probe incorporates each of the foregoing General Objections into its response.
 9 Gen-Probe further objects to this Request on the grounds that it is overly broad and not
 reasonably calculated to lead to the discovery of admissible evidence. *Documents responsive to*
 10 *this request that concern Gen-Probe's commercial embodiments of the Cap Patents and were*
 11 *created after the effective filing date of those patents are irrelevant.* See e.g., *Phillips Petroleum*
 12 *Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1291-92 (D. Del. 1987); *Singh v. Brake*, 317 F.3d
 13 1334, 1345 (Fed. Cir. 2002). Gen-Probe further objects to this Request on grounds that
 "prototype" is vague and ambiguous in the context of this Request. Gen-Probe interprets this
 term as referencing an embodiment developed prior to the effective filing date of the Cap
 Patents. Gen-Probe also objects to this Request on grounds that it calls for production of
 information protected by the attorney-client privilege, the work product doctrine, and/or other
 14 privileges and immunities. (Emphases added).

15 **A. BD's Statement of Reasons to Compel Discovery:**

16 BD's Request No. 67 and similar requests seek documents concerning the design and
 17 development of any of Gen-Probe's penetrable cap products that Gen-Probe contends embody of
 18 the invention(s) claimed in the asserted "Cap Patents." In response, Gen-Probe stated that it
 19 would produce documents from the official files for only 2 assay kit products, even though it
 20 identified 17 assay kits that include caps embodying a Cap Patent invention in its Preliminary
 21 Infringement Contentions. Gen-Probe subsequently agreed to produce additional responsive
 22 documents outside those official files, but only such documents that were created "*before the*
 23 *effective filing date*" of the Cap Patents, which Gen-Probe contends to be March 9, 2001.¹³

24 Gen-Probe cannot limit its production to two assay products that it unilaterally decides
 25 are "representative" of all seventeen "patented" products. Moreover, for the reasons stated in
 26

27 ¹² Gen-Probe's objection and response to Request No. 67 is representative of other responses in
 28 which Gen-Probe purports to limit its responses to documents created before "the effective filing
 date" of the Cap Patents. These requests include Request Nos. 62, 63, 64, 65, 68, 69, 72, and 73.

¹³ See *supra*, note 3.

1 Section I, Gen-Probe has an obligation to produce critical documents concerning design and
 2 development efforts after March 9, 2001, including the years immediately preceding its product
 3 launches as well as the current design of Gen-Probe's commercial embodiments. For these
 4 reasons, BD requests that the Court overrule Gen-Probe's objections to Request Nos. 62, 63, 64,
 5 65, 67, 68, 69, 72, and 73 and order Gen-Probe to produce responsive documents, including
 6 those created after the effective filing date of the Cap Patents.

7
 8 **B. Gen-Probe's Statement of Reasons for Objecting to Discovery:**

9 BD's argument concerning "17 assay kits" is either based upon its fundamental
 10 misunderstanding or its deliberate attempt to misdirect the Court. The penetrable caps used in
 11 what BD calls the "2 assay kit products" are the same as those used in all "17 assay kits."
 12 (Kacian Decl. ¶ 5.) Gen-Probe has agreed to produce the relevant documents. Gen-Probe's
 13 arguments against BD's overbroad requests for documents concerning Gen-Probe's
 14 embodiments of its Penetrable Cap Patents are essentially the same as those concerning Gen-
 15 Probe's TIGRIS embodiment of the Automation Patents, discussed in Section I above.

16 As an initial matter, BD's suggestion – in a footnote – that its Request No. 67 is "similar"
 17 to its other requests for documents concerning Gen-Probe's penetrable caps is facially
 18 misleading. As BD's Request No. 72 makes clear, BD is *really* seeking:

19 All documents concerning the testing, manufacture, use, sale or
 20 offer for sale of Gen-Probe's Penetrable Caps, including all
 21 engineering notebooks, notes, memoranda, correspondence, e-
 22 mails, prototypes, invention disclosure statements, engineering
 23 change orders, bills of material, research reports, development
 24 proposals, project approvals, project summaries, new product
 25 disclosures or proposals, drawings, sketches, schematics, models,
 computer models, simulations, manufacturing specifications or
 protocols, testing specifications or protocols, technical manuals,
 product manuals, service manuals, operation manuals, samples,
 presentations, data files, meeting minutes, diaries, calendars,
 publications, product specifications, product development
 documents, theory of operation documents, failure modes and
 effects documents, and any other design and technical documents.

26 (Ex. A, Request No. 72, at 56-57.) Here again, BD offers no support for its claim that "all
 27 documents" concerning Gen-Probe's penetrable caps, unbound by time and untethered to any

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1 claim or defense, are relevant. As is the case with TIGRIS instrument, Gen-Probe's penetrable
2 caps are *not* on trial in this action against BD for *its* infringement of Gen-Probe's patents.

3 Once more, BD fundamentally misconstrues the scope of documents that Gen-Probe has
4 stated that it will produce in response to BD's requests. As set forth in the accompanying
5 declarations of Daniel Kacian and Tina Ninteman, Gen-Probe will produce all the documents BD
6 could reasonably claim are relevant and non-cumulative including: (1) the portions of the design
7 history and project files for Gen-Probe's APTIMA Combo 2® and PROGENSA® PCA3
8 assays¹⁴ that relate to the only two versions of penetrable cap covered by the Penetrable Cap
9 Patents that Gen-Probe has ever commercialized, (Kacian Decl. ¶ 5; Ninteman Decl. ¶ 6; Long
10 Decl. ¶ 3(d)); (2) all documents relating to the conception, reduction to practice, research,
11 development, or manufacture of the inventions of the asserted Penetrable Cap Patents, including
12 embodiments thereof, created on or before March 8, 2002 – the latest arguable “effective filing
13 date”¹⁵ for the Penetrable Cap Patents, (Ex. A, Request No. 40, at 34; Long Decl. ¶ 3(a)); (3) its
14 entire FDA submissions for the TIGRIS Instrument as well as the APTIMA Combo 2 assay for
15 inspection and copying, (*id.* ¶ 3(f); Bowen Decl.; ¶¶ 5-6); and (4) Gen-Probe will also search for
16 design history files for any version of Gen-Probe's penetrable caps that may exist outside of the
17 design history files and project files for the Combo 2 and PROGENSA assays, (Long Decl. ¶ 4.)

18 Thus, Gen-Probe has already agreed to conduct a reasonable search for documents
19 responsive to BD's overbroad and irrelevant requests for “all documents” concerning Gen-
20 Probe's penetrable caps. The Court should deny this aspect of BD's motion.

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23
24 ¹⁴ These files contain the same level of content, detail and disclosure as the TIGRIS design history file
25 and project file including all information concerning the design, manufacture, operation and use material
26 to safety and efficacy of the Combo 2 and PROGENSA assays and their components. (Ninteman Decl. ¶
27 6.)

28 ¹⁵ The original patent application leading to both of the Penetrable Cap Patents was filed on March 8,
2002. That patent application further claims priority to a “provisional” application filed on March 9, 2001
that has all the same material disclosure as set forth in the specification of the March 8, 2002 application.
Thus, the “effective filing date” of both Penetrable Cap Patents is March 9, 2001 at the earliest, and
March 8, 2002 at the latest.

1 **C. BD's Reply to Gen-Probe's Statement of Reasons:**

2 BD cannot (and this Court should not) simply rely on Gen-Probe's assertions that there
3 are no relevant, responsive documents concerning the design and development of Gen-Probe's
4 cap products other than those contained in the "official" files of its APTIMA Combo 2 and
5 PROGENSA assays. Gen-Probe refuses to produce two significant categories of documents
6 including: (1) documents concerning the design and development of Gen-Probe's penetrable cap
7 products between March 2002 and the present that may be located outside those two "official"
8 files of its APTIMA Combo 2 and PROGENSA assays (as located after a reasonable search);
9 and (2) documents from the "official" files of 15 of the 17 products that Gen-Probe identified as
10 commercial embodiments of its cap patents.

11 For the reasons stated in Section I, above, documents concerning the commercial
12 embodiments of the asserted patents (each of which will presumably be included in Gen-Probe's
13 damages claim) are directly relevant to a variety of issues in this case. Also as noted above,
14 Gen-Probe has not suggested that it will suffer any undue burden by searching for responsive
15 documents after its self-imposed cut-off date, or in additional files.

1 **III. Gen-Probe's Refusal to Produce Documents Concerning the Use of Bleach With Its**
 2 **Commercial Products**

3 **Request No. 96:**¹⁶ All documents concerning the development, testing, research or
 4 commercialization of any alleged invention claimed in the Bleach Patent, including but not
 5 limited to notes, memoranda, emails, notebooks, invention disclosure statements, meeting
 minutes, submissions to the FDA, diaries, publications, product development documents, and
 calendars.

6 **Response:** Gen-Probe will produce non-privileged and responsive documents concerning
 7 development, testing, or research *regarding the first commercial embodiment* of the claimed
 invention in its possession, custody, or control that can be identified after a reasonable search.

8 Gen-Probe's response to this Request is made subject to and without waiver of the following
 9 Objections: Gen-Probe incorporates each of the foregoing General Objections into its response.
 Gen-Probe further objects to this Request on the grounds that it is overly broad, unduly
 10 burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.
 11 *Documents responsive to this request that concern Gen-Probe's commercial embodiments of*
 12 *the Bleach Patent and were created after the effective filing date of those patents are*
 13 *irrelevant.* See e.g., *Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1291-92 (D.
 Del. 1987); *Singh v. Brake*, 317 F.3d 1334, 1345 (Fed. Cir. 2002). Gen-Probe also objects to this
 14 Request on grounds that it calls for production of information protected by the attorney-client
 privilege, the work product doctrine, and/or other privileges and immunities. (Emphases Added).

15 **A. BD's Statement of Reasons to Compel Discovery:**

16 BD's Request No. 96 (and similar requests) seeks documents concerning Gen-Probe's
 17 development of products embodying the inventions claimed in its '200 patent (the "bleach"
 18 patent). As with Gen-Probe's other attempts to limit discovery concerning its commercial
 19 embodiments, see Sections I & II, Gen-Probe's refusal to permit full discovery of products
 20 allegedly embodying the '200 patent invention is also improper. Indeed, Gen-Probe refuses to
 21 permit even discovery sufficient to confirm Gen-Probe's allegation that those products have
 22 consistently utilized the claimed inventions. Gen-Probe's responses to Request No. 96 (and
 23 similar requests) improperly place the temporal limitation ("not created after the effective filing
 24 date") for documents outside of the official "Design History" and "Project" files, effectively

25 ¹⁶ Gen-Probe's objection and response to Request No. 96 is representative of other responses in
 26 which Gen-Probe refuses to produce responsive documents concerning the use of sodium
 27 hypochlorite or bleach in connection with its products, including Request Nos. 98, 100, (refusal
 to produce responsive documents after the effective filing date of the '200 patent); 101-104, 106
 28 and 181 (refusal to produce documents other than "public package inserts" created before the
 effective filing date); 105 (refusal to produce documents other than the first commercial
 embodiment of the '200 patent).

1 excluding all documents concerning the many products it launched after the '200 patent's
2 "effective filing date."

3 In addition, a number of Gen-Probe's responses to requests for documents concerning
4 embodiments of the '200 patent purport to further limit Gen-Probe's production obligations to
5 "public package inserts." Req. Nos. 101-104, 106 and 181. Non-public documents concerning
6 Gen-Probe's development of commercial products utilizing the alleged invention(s) of the bleach
7 patent are relevant to numerous issues including BD's § 112 enablement, written description, and
8 best mode defenses, as well as Gen-Probe's contentions of non-obvious and its damages claims.
9 Therefore, BD requests the Court to compel production of all documents responsive to Requests
10 96, 98, 100-106, and 181.

11
12 **B. Gen-Probe's Statement of Reasons for Objecting to Discovery:**

13 Here again, BD's requests for "all documents" – this time concerning Gen-Probe's use of
14 bleach in accord with the asserted Bleach Patent – are unbound by time and untethered to any
15 claim or defense in this action, and are therefore facially overbroad. To repeat a recurrent theme
16 in this motion, Gen-Probe's prescriptions for using bleach are *not* on trial in this case. Rather,
17 the relevant inquiry concerns a comparison of *Gen-Probe's patents* and *BD's accused products*.

18 APTIMA Combo 2, approved for manual use in August 2001,¹⁷ prescribes the use of
19 bleach in accord with the Bleach Patent and is representative of other such assays that use bleach
20 that were launched both before and after that date. (Kacian Decl. ¶ 6.) Notwithstanding BD's
21 erroneous claims of the relevance of "all documents" relating to development work on the use of
22 bleach after the Bleach Patent filing date, Gen-Probe will produce all the documents that BD
23 could deem relevant to its defenses, including: (1) documents from the APTIMA Combo 2
24 design history file and project file relating to the use of bleach in connection with that assay, (*Id.*;
25 Long Decl. ¶ 3(d).); (2) the TIGRIS design history and project files (described as set forth
26 above), which also detail the use of bleach with that instrument consistent with the Bleach
27 Patent, (Kacian Decl. ¶ 8; Long Decl. ¶ 3(c)); (3) All documents relating to the conception,

28 ¹⁷ By comparison, the original application leading to the Bleach Patent was filed on June 24, 1992.

1 reduction to practice, research, development, or manufacture of the inventions of the asserted
 2 Bleach Patent, including embodiments thereof, created on or before June 24, 1992, (*see, e.g.*, Ex.
 3 A, Request No. 82, at 63; Long Decl. ¶ 3(a)); (4) any design history file or project file specific to
 4 the research, development or use of bleach independent of the corresponding files for its TIGRIS
 5 instrument and the individual assays commercialized by Gen-Probe, including any such files that
 6 might include comparisons to alternates to bleach, (*id.* ¶ 4.); (5) its entire FDA submissions for
 7 the TIGRIS Instrument as well as the APTIMA Combo 2 assay for inspection and copying, (*id.* ¶
 8 3(f); Bowen Decl.; ¶¶ 5-6); and (6) package inserts – which are FDA-approved documents – for
 9 all of Gen-Probe’s assays that prescribe the use of bleach, and thus contain all the information
 10 BD needs to confirm or deny whether Gen-Probe’s products “have consistently utilized the
 11 claimed inventions” in the Bleach Patent, (Kacian Decl. ¶ 9; Long Decl. ¶ 3(h).)

12 Despite the public availability of the package inserts for Gen-Probe’s bleach-using
 13 assays, BD has failed to identify *any* evidence to support or suggest an inconsistent use of the
 14 Bleach Patent, or otherwise to justify its overreaching, “scorched earth” campaign for “all
 15 documents” concerning Gen-Probe’s use of bleach. Thus, notwithstanding BD’s unsupported
 16 statement that such documents are all relevant to BD’s various alleged § 112 defenses, Gen-
 17 Probe has committed to undertake a review and production that is far more than the law requires.

18
 19 **C. BD’s Reply to Gen-Probe’s Statement of Reasons:**

20 As Gen-Probe admits, more than nine years passed between the claimed June 1992
 21 priority date of the ’200 patent and Gen-Probe’s first commercial embodiment in August 2001.
 22 Gen-Probe refuses to produce any documents from this nine year period (or thereafter) other than
 23 those contained in the “official” files for its TIGRIS instrument and APTIMA Combo 2 assay,
 24 two of the 40 products Gen-Probe identified as commercial embodiments of the ’200 patent.
 25 Gen-Probe cannot withhold documents concerning this substantial gap in its product
 26 development, including any alternatives to bleach used and any problems encountered
 27 implementing the use of bleach. As stated above in Section I, such documents bear directly on
 28 Gen-Probe’s claims and Gen-Probe has not alleged any undue burden.

1 **IV. Gen-Probe's Refusal to Produce Documents Concerning the Prior Art Anderson**
 2 **Patent Assigned to Gen-Probe**

3 **Request No. 77:**¹⁸ All documents concerning the alleged conception, reduction to practice and
 4 development work of each of the named inventors of the Anderson Patents and any persons who
 5 assisted them, including but not limited to laboratory notebooks, invention disclosures,
 6 experimental protocols, and data analysis.

7 **Response:** Gen-Probe will produce non-privileged and responsive documents *to the extent they*
 8 *also concern the inventions of the Cap Patents* in its possession, custody, or control that can be
 9 identified after a reasonable search.

10 Gen-Probe's response to this Request is made subject to and without waiver of the following
 11 Objections: Gen-Probe incorporates each of the foregoing General Objections into its response.
 12 Gen-Probe further objects to this Request on the grounds that it is overly broad, unduly
 13 burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. The
 14 Anderson Patents are not asserted in this litigation. Gen-Probe further objects to this Request.

15 **A. BD's Statement of Reasons to Compel Discovery:**

16 BD's Request Nos. 77 and 79-81 seek documents concerning the inventions described in
 17 the "Anderson Patents," a patent family including U.S. Patent No. 6,806,094 assigned to Gen-
 18 Probe, which discloses a prior art penetrable cap and which BD identified as a prior art reference
 19 that anticipates and/or renders obvious all asserted claims of the asserted Cap Patents. During
 20 the prosecution of the patent applications which issued as the Cap Patents, the Patent Office
 21 characterized the Anderson Patent as the closest prior art and repeatedly cited it as prior art. In
 22 response, Gen-Probe drew narrow distinctions between the Anderson disclosure and the claims
 23 of the Cap Patents.

24 Documents concerning design and development work that led to conception and
 25 reduction to practice of the caps claimed in the Anderson Patent family have the potential to
 26 demonstrate that the asserted patents' claimed inventions had already been conceived by a
 27 different inventive entity focused on exactly the same "problem": a penetrable cap for use in an
 28 automated nucleic acid diagnostic instrument. Such prior conception would constitute
 29 invalidating prior art under 35 U.S.C. § 102(g). Gen-Probe refuses to provide the requested
 30 documents concerning conception and reduction to practice of the Anderson invention. BD's

¹⁸ Gen-Probe's objection and response to Request No. 77 is representative of its responses to
 Request Nos. 79-81, which also seek documents concerning Gen-Probe's Anderson Patents.

1 requests for documents concerning work related to the Anderson Patents are not overbroad and
 2 relate directly to closest prior art to the asserted patents. BD therefore requests that the Court
 3 order Gen-Probe to produce documents responsive to BD's Request Nos. 77 and 79-81.

4
 5 **B. Gen-Probe's Statement of Reasons for Objecting to Discovery:**

6 BD's request for "all documents" concerning the Anderson Patents is not only overbroad,
 7 it is also demonstrably irrelevant. As BD concedes, the *Anderson Patent itself* – that is, the
 8 publicly available, published U.S. Patent No. 6,806,094 – was deemed by the PTO to be the
 9 "closest" prior art in connection with the prosecution of Gen-Probe's '308 Penetrable Cap Patent.
 10 As such, the relevant aspect about the Anderson Patents is the patent itself and its prosecution
 11 history, and Gen-Probe has agreed to produce those documents. (Long Decl. ¶ 5.)

12 BD argues that *non-public documents* underlying the conception and reduction to practice
 13 of the Anderson Patents could "potentially" demonstrate that the invention described in those
 14 patents invalidates the Penetrable Cap Patents under 35 U.S.C. § 102(g). BD is flat wrong on the
 15 law. As 35 U.S.C. § 103(c)(1) makes clear, subject matter:

16 developed by another person, which qualifies as prior art only
 17 under one or more of subsections (e), (f), and (g) of section 102 of
 18 this title, ***shall not preclude patentability under this section*** where
 19 the subject matter and the claimed invention were, ***at the time the
 claimed invention was made, owned by the same person or
 subject to an obligation of assignment to the same person.***

20 In other words, the non-public documents cannot be a basis for invalidating under § 102(g),
 21 because (as BD concedes) the Anderson Patents are owned by Gen-Probe – the same owner as
 22 the Penetrable Cap Patents. Publicly available information shows that the Anderson Patents had
 23 been assigned to Gen-Probe no later than July 2000, long before the filing of the original
 24 application giving rise to the Penetrable Cap Patents in March 2002. (Bowen Decl. ¶ 4, Ex. 3.)
 25 Thus, BD's claimed basis for production lacks factual and legal support.

26 Moreover, Gen-Probe has agreed to produce the only other arguably relevant documents
 27 relating to the Anderson Patents – *e.g.*, any documents that compare the cap disclosed in the

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Anderson Patent to the cap claimed in the Penetrable Cap Patents. No other documents concerning the unrelated, unasserted Anderson Patents is warranted or justified.

C. BD's Reply to Gen-Probe's Statement of Reasons:

Gen-Probe's quotation of § 103(c)(1) of the patent statute¹⁹ does not justify its refusal to produce the requested material concerning Gen-Probe's design and development work relating to the cap described and claimed in the Anderson Patents.

First, the statutory language Gen-Probe cites applies only if the invention claimed in the asserted cap patents ('308 and '612 patents) and the subject matter of the prior art Anderson Patents were both assigned to Gen-Probe "at the time the claimed invention was made." Gen-Probe claims the invention of the '308 and '612 patents was made no later than *September 1999*. See Carroll Decl., Ex. D, Gen-Probe's Response to Interrogatory No. 1, p. 6. The subject matter of the Anderson Patents was not assigned to Gen-Probe until almost one year later, in *July 2000*. Bowen Decl., ¶ 4, Ex. 3. The language Gen-Probe relies on is therefore inapplicable.

Further, section 103 relates only to "obviousness." To the extent the early development work that led to the Anderson Patents included discussion of or experiments with the design(s) later claimed by Kacian et al. in the '308 and '612 patents, such earlier work would anticipate and invalidate the '308 and '612 patent claims under 35 U.S.C. § 102(g). BD is entitled to discovery concerning the Anderson inventors' earlier work in developing and testing penetrable cap designs that are "prior art." Gen-Probe's attempt to limit discovery to the published Anderson Patent itself and/or express comparisons to the asserted patents, without any identification of burden or prejudice, only further suggests the existence of relevant documents.

¹⁹ The language of section 103 cited by Gen-Probe was added by an amendment enacted Nov. 29, 1999, which amendment expressly applied only to "application[s] for patent filed on or after the date of the enactment of this Act." P.L. 106-113, Div. B, § 1000(a)(9), 113 Stat. 1536. In this case, the Anderson Family of patents and applications share an "effective filing date" prior to that amendment, May 14, 1999. Therefore, the cited language does not preclude application of the Anderson Patents, or related work as, prior art rendering the asserted patents obvious.

V. **Gen-Probe's Refusal to Produce Documents Concerning Customer Communications, Complaints, Technical Problems, Quality Concerns, or Contamination of its Commercial Embodiments**

Request No. 26²⁰: All user manuals, package inserts, training documentation, maintenance instructions, technical bulletins, *and other written information provided to customers or users* of the TIGRIS instrument.

Response: Gen-Probe will produce user manuals, package inserts, training documentation, maintenance instructions, and technical bulletins for the TIGRIS Instrument in its possession, custody, or control that can be identified after a reasonable search.

Gen-Probe's response to this Request is made subject to and without waiver of the following Objections: Gen-Probe incorporates each of the foregoing General Objections into its response. Gen-Probe further objects to this Request on the grounds that it, including at least the phrase "other written information provided to customers or users of the TIGRIS Instrument," is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Documents responsive to this request that concern Gen-Probe's commercial embodiments of the Process Patents and were created after the effective filing date of those patents are irrelevant. *See, e.g., Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1291-92 (D. Del. 1987); *Singh v. Brake*, 317 F.3d 1334, 1345 (Fed. Cir. 2002). (Emphasis added)

A. **BD's Statement of Reasons to Compel Discovery:**

Gen-Probe's response to Request Nos. 26, 65 and 107 refuses to produce the requested "other written information provided to customers or users" of the Gen-Probe products that embody its alleged inventions. These "other" requested documents include, for example, documents concerning customer complaints and technical problems for which Gen-Probe presumably maintains files. Such documents are relevant to a number of issues, including enablement, secondary considerations of non-obviousness, and Gen-Probe's damages claims, if any. *See Single Chip Systems Corp. v. Intermec IP Corp.*, 2006 WL 4660129, *19 (S.D. Cal. 2006); *Chiron Corp.*, 363 F.3d at 1260-1261. For these reasons and those set forth in Sections I-III above, BD requests that the Court overrule Gen-Probe's objections to Request Nos. 26, 65, and 107 and order Gen-Probe to produce responsive documents.

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²⁰ Gen-Probe's objection and response to Request No. 26 is representative of other responses in which Gen-Probe refuses to produce other written information provided to customers of products embodying the alleged inventions. These requests include Request Nos. 65 (penetrable caps) and 107 (use of bleach with Gen-Probe's products).

1 **B. Gen-Probe's Statement of Reasons for Objecting to Discovery:**

2 BD's demand for all "*other written information provided to customers or users* of the
3 TIGRIS instrument" in Request No. 26 renders that request and others like it hopelessly vague
4 and overbroad. Indeed, it could encompass every email Gen-Probe has dating back to the start of
5 clinical trials of TIGRIS in 2003 and prior that was addressed to any TIGRIS customer or user
6 *for any reason* and addressing any subject. Gen-Probe has already agreed to produce user
7 manuals, package inserts, training documentation, maintenance instructions, and technical
8 bulletins for TIGRIS. (Long Decl. ¶ 3(h).) In light of that production, BD has not and cannot
9 establish that all "other" written documents are relevant to any claim or defense in this case.

10 BD's justification that such "other" documents might "include, for example, documents
11 concerning customer complaints and technical problems for which Gen-Probe presumably
12 maintains files" does nothing to remediate the request. *First*, Request No. 26 as well as Request
13 Nos. 65 and 107 address "other written information *provided to* customers or users." Thus, BD's
14 requests do not encompass a "customer complaint" *sent from* a customer or user. *Second*, as
15 required by the FDA, Gen-Probe maintains its files regarding "TIGRIS Complaints" as part of
16 the TIGRIS design history file that Gen-Probe has already agreed to produce. (See Ninteman
17 Decl., ¶ 2, Ex. 1 at p. 10-11 (addressing Volume 43 of the TIGRIS design history file).) BD's
18 vague and overbroad request for "other written information" sent to Gen-Probe's customers or
19 users should therefore be denied.

20
21 **C. BD's Reply to Gen-Probe's Statement of Reasons:**

22 During the parties' meet-and-confer, BD clarified that it was seeking several specific
23 categories of "other written information" within the scope of Request No. 26 including
24 communications concerning technical issues or customer complaints. While it may be true that
25 responsive documents are located in the TIGRIS Design History File, Gen-Probe cannot skirt its
26 obligation to produce responsive documents *outside* of the Design History File by refusing to
27 commit itself to a reasonable search of its other files. To the extent there are no additional
28 documents outside the "Design History File," there is no additional burden on Gen-Probe and no

1 reason for Gen-Probe's objection. Indeed, Gen-Probe once more fails to demonstrate that the
2 search for or production of the requested documents would be unduly burdensome. *See*
3 *Tourgeman v. Collins Financial Services*, 2010 WL 2181416, *4, (S.D. Cal. May 25, 2010)
4 (Stormes) ("If [parties] object to production, they must base their objections on specific facts,
5 such as the numerosity of a particular type of document, to facilitate a meaningful evaluation of
6 what may be considered relevant or an undue burden").
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1 **VI. Gen-Probe's Refusal to Produce Documents Concerning its Customers, Sales,**
 2 **Training, and Marketing**

3 **Request No. 76:** ²¹ All documents concerning sales training materials or communications
 4 concerning sales strategies with Gen-Probe sales personnel, third-party sales personnel or
 distributors, concerning Gen-Probe's Penetrable Caps.

5 **Response:** Gen-Probe will produce non-privileged, responsive documents in the possession,
 6 custody, or control of *Gen-Probe sales and marketing managers that were created after*
 7 *December 2008 and refer to any of the Accused Products* that can be identified after a
 reasonable search.

8 Gen-Probe's response to this Request is made subject to and without waiver of the following
 9 Objections: Gen-Probe incorporates each of the foregoing General Objections into its response.
 10 Gen-Probe further objects to this Request on the grounds that it is overly broad, vague and
 11 ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of
 12 admissible evidence. Gen-Probe further objects to this Request on grounds that the burden or
 expense of the proposed discovery outweighs its likely benefit. Gen-Probe also objects to this
 Request on grounds that it calls for production of information protected by the attorney-client
 privilege, the work product doctrine, and/or other privileges and immunities. (Emphasis added).

13 **A. BD's Statement of Reasons to Compel Discovery:**

14 Gen-Probe limits its responses to Request No. 76 and similar requests with 3 arbitrary
 15 limitations on documents relating to Gen-Probe's sales strategies and sales training materials
 16 concerning its commercial embodiments: (1) Gen-Probe agrees only to produce documents in the
 17 custody of its "sales and marketing managers," thereby excluding any responsive documents
 18 contained in shared or common files (or shared servers or databases) or in the possession of key
 19 marketing personnel that are not "managers"; (2) Gen-Probe refuses to produce documents
 20 created prior to December 2008, although the TIGRIS instrument launched in early 2004; and (3)
 21 Gen-Probe agrees to produce only responsive materials that also concern one of the BD Accused
 22 Products.

23 Documents concerning Gen-Probe's sales strategies prior to and after its product launch
 24 are highly relevant to any lost profits claim and any asserted secondary considerations of non-
 25 obviousness, *see In re Baxter Travenol Laboratories*, 952 F.2d 388, 392 (Fed. Cir. 1991)
 26 (commercial success argument requires market share information), and documents concerning
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28 ²¹ Gen-Probe's response to Request No. 76 is representative of its response to Request Nos. 30,
 75-76, 118-120, 123, and 157-159.

1 the relative market share of its competitors and the existence of non-infringing alternatives to the
2 accused infringing products are highly relevant to Gen-Probe's claims for damages, if any.

3 **B. Gen-Probe's Statement of Reasons for Objecting to Discovery:**

4 BD's requests suffer from three fatal problems. *First*, BD's requests for any documents
5 "relevant to any lost profits claim and any asserted secondary considerations of non-
6 obviousness" are premature. Gen-Probe has not yet made a decision on whether it will seek lost
7 profits as the measure of its damages for BD's infringement, and it *cannot* do so until it receives
8 discovery from BD concerning its sales of accused products.²² However, to date, BD has not
9 produced its documents concerning those sales, despite Gen-Probe's request for that information
10 over six months ago in January 2010. (Long Decl. ¶ 10.) Gen-Probe agrees that, once it
11 determines whether it will claim lost profits, further discovery related to that claim may become
12 relevant. At this time, it is not.

13 *Second*, with regard to BD's requests for documents relevant to "any asserted secondary
14 considerations of non-obviousness," Gen-Probe has also not yet determined what, if any,
15 secondary considerations it may assert in rebuttal to BD's contentions of obviousness. As such,
16 those requests are also premature. (See Gen-Probe's opposition to BD's motion to compel
17 further responses to its interrogatories numbered 2 and 3 concerning such unasserted secondary
18 considerations. (See Dkt. No. 56 at 12-15, 17-18).) If and when Gen-Probe determines that it
19 will rely on secondary considerations to rebut BD's affirmative defense of invalidity, Gen-Probe
20 will produce relevant documents germane to those secondary considerations.

21 *Third*, even if questions of lost profits and secondary considerations were relevant at this
22 stage in the litigation, BD's Request No. 76 and most of its "similar requests" seeking "all
23 documents" concerning Gen-Probe's sales and marketing of its own products are overbroad – so
24 broad, for example, as to encompass every email since the beginning of time in the possession,
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27 ²² 35 U.S.C. § 284 provides that, upon a finding of BD's infringement, Gen-Probe shall be awarded
28 "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty...."
Thus, Gen-Probe has the option to seek, at its election, its lost profits arising from any of BD's infringing
sales ("damages adequate to compensate for the infringement"), or, a reasonable royalty. Gen-Probe
needs discovery of BD's infringing sales before it can make that determination.

1 custody or control of Gen-Probe's sales and marketing personnel that mentions "TIGRIS" (e.g.,
 2 BD's Request No. 30) or Gen-Probe's penetrable caps (e.g., BD's Request No. 76). And yet, as
 3 part of the parties' meet-and-confer efforts on this dispute, BD has stated:

4 BD is not suggesting that, in response to these requests, Gen-Probe
 5 must conduct unreasonable searches or interview every company
 6 employee for any piece of paper that refers in passing to a
 responsive topic. BD only requests that Gen-Probe conduct a
 reasonable search for responsive documents.

7 (Long Decl. ¶ 6). In fact, Gen-Probe's agreement to search for documents in the possession,
 8 custody, or control of its sales and marketing managers (which includes shared and "department"
 9 files) limited to a certain time period and which also reference BD's accused instrument and
 10 assay products *is* a reasonable response to those requests, and BD has given no justification for
 11 challenging the reasonableness of that proposed search.²³ Indeed, Gen-Probe has invited BD to
 12 suggest a reasonably expanded list of custodians and to justify a date cut-off prior to the launch
 13 of BD's Viper XTR instrument in December 2008 without regard to whether the documents
 14 reference any BD product, but BD has declined to do so. (*Id.* ¶ 8.)

15 **C. BD's Reply to Gen-Probe's Statement of Reasons:**

16 Gen-Probe is not entitled to wait until the close of fact discovery to simply "elect" to
 17 make a damages claim (lost profits or reasonable royalties) or to assert evidence of secondary
 18 considerations of non-obviousness (i.e., commercial success). Gen-Probe currently possesses
 19 *factual* information and documents relevant to both issues, including the purported "benefits" of
 20 the claimed inventions as identified by Gen-Probe's sales force, its historic sales strategies, its
 21 competitive positioning in the market dating back prior to product launch in 2003, and lost sales
 22 (if any) as a result of the alleged infringement. Gen-Probe's damages and non-obviousness
 23 claims are not contingent upon further discovery from BD. As close competitors, Gen-Probe is

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 26 ²³ BD's pursuit of this discovery dispute exemplifies the fundamental contrast between the parties'
 27 approaches to responding to their respective document discovery obligations. In response to Gen-Probe's
 28 document requests, BD principally responded by stating that it would conduct a "reasonable search" for
 documents responsive to those requests, leaving Gen-Probe to guess at what a "reasonable search"
 actually means to BD. By contrast, in response to many of BD's document requests, Gen-Probe
 responded by candidly detailing what its "reasonable search" would be.

1 aware of BD's sales activities. Indeed, BD provided an interrogatory answer containing contact
2 information for laboratories in which the accused Viper XTR instruments have been placed.

3 Gen-Probe must conduct a reasonable search for documents relevant to these issues now
4 – including documents beyond those in the possession of Gen-Probe “managers” or documents
5 that also relate to a BD accused product – or acknowledge that it: (1) will not pursue a damages
6 claim; and/or (2) will not rely on evidence of secondary considerations of non-obviousness.
7 Again, Gen-Probe's response does not identify any specific alleged burden other than its
8 dramatic claim that the requests seek “every email since the beginning of time.” The scope of
9 Gen-Probe's ESI search (including email) will be agreed upon separately by the parties, and will
10 not include “all” email.
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VII. Gen-Probe's Objection that Requests for Documents are "Premature"

Request No. 168:²⁴ Documents sufficient to identify each and every customer that Gen-Probe alleges ceased purchasing Gen-Probe products, diminished its purchases of Gen-Probe products, or sought lower prices for its purchases of Gen-Probe products as a result of BD's sales of any Accused Products, and documents concerning each such customer's decision to cease or diminish its purchases or seek lower prices.

Response: To the extent that documents responsive to this Request are not otherwise produced in response to other Requests, Gen-Probe will produce documents responsive to this Request *in accordance with the Court's schedule concerning exchange of expert reports*. Otherwise, Gen-Probe objects that this Request is premature in light of the Court's schedule concerning exchange of expert reports. In addition, Gen-Probe incorporates each of the foregoing General Objections into its response. Gen-Probe also objects to this Request on grounds that it calls for production of information protected by the attorney-client privilege, the work product doctrine, and/or other privileges and immunities. (Emphasis added).

A. BD's Statement of Reasons to Compel Discovery:

Gen-Probe's refusal to produce documents concerning any alleged damages, lost customers, or lost sales in response to Request Nos. 166-168 – until *after* the close of fact discovery – is improper. The Court's Scheduling Order does not delay such fact discovery as to Gen-Probe's claim for damages, if any. If Gen-Probe believes it has lost customers or sales as a result of any alleged infringement, Gen-Probe must produce relevant documents without delay. Gen-Probe's improper response to Request No. 168 is representative of numerous responses in which Gen-Probe refuses to produce "secondary considerations" documents on the ground that the "Request is premature because BD has not yet set forth a *prima facie* case of obviousness." See Req. Nos. 15-16, 56-57, and 94-95. Despite disclosure by BD of its obviousness defenses in its November 2009 Answer and June 2010 Preliminary Invalidity Contentions, Gen-Probe argues that it need not produce such documents until it decides to assert secondary considerations. Gen-Probe cannot unilaterally defer this fact discovery until an undefined time of its choosing.²⁵

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²⁴ Gen-Probe's objection and response to Request No. 168 is representative of other responses including Request Nos. 15-16 (documents concerning secondary considerations of non-obviousness as to the Process Patents), 56-57 (documents concerning secondary considerations as to the Cap Patents), 94- 95 (secondary considerations as to the '200 Patent), and 166-168 (Gen-Probe's claims for damages).

²⁵ See, e.g., *Willard v. Constellation Fishing Corp.*, 136 F.R.D. 28, 31 (D.Mass. 1991) (a party seeking deferral of disclosure has the burden of seeking the Court's permission to delay).

1 Gen-Probe's responses and objections to Request Nos. 15-16, 56-57, 94-95, and 166-168 are
 2 improper, and BD requests an order compelling Gen-Probe to produce responsive documents.

3 **B. Gen-Probe's Statement of Reasons for Objecting to Discovery:**

4 BD's attempt to require Gen-Probe to search for and produce documents "sufficient to
 5 identify each and every customer that Gen-Probe alleges ceased purchasing Gen-Probe products"
 6 is premature for all the same reasons set forth above in connection with BD's Request for Gen-
 7 Probe's sales and marketing documents, *supra* Section VI. BD's Request No. 168 is essentially
 8 a contention interrogatory in the form of a document request that seeks "documents sufficient to
 9 identify" customers that Gen-Probe *contends* it lost to BD.

10 As noted above, until BD produces documents concerning its sales of accused products,
 11 Gen-Probe will not be in a position to determine which, if any, customers it lost to BD as a result
 12 of BD's infringement. Assuming that BD makes that production reasonably early during the fact
 13 discovery period, Gen-Probe should be able to determine whether it will pursue lost profit
 14 damages during the fact discovery period as well, and produce responsive documents.

15 Finally, setting aside the prematurity of BD's request, BD has no credible argument that
 16 "documents sufficient to identify" any customer lost to BD are relevant to any secondary
 17 considerations of nonobviousness.

18 **C. BD's Reply to Gen-Probe's Statement of Reasons:**

19 As stated above (Sec. VI), Gen-Probe's lost profits claim is not contingent upon further
 20 discovery from BD, nor is Gen-Probe entitled to wait until the close of fact discovery to decide
 21 to claim lost profits. Gen-Probe should be compelled to produce responsive documents now or
 22 abandon its claim for lost profits.

VIII. Gen-Probe's Refusal to Produce Documents Pertaining to Patents "Related" to the Asserted Automation Process Patents.

Request No. 12:²⁶ All documents concerning any meetings or telephone conferences Gen-Probe, its representatives, or the Named Inventors attended or participated in with the PTO or with any foreign patent office concerning the Process Patents or *Related Patents*. (Emphasis added)

Response: Gen-Probe will produce non-privileged and responsive documents in its possession, custody, or control that can be identified after a reasonable search, to the extent such documents have not already been produced.

Gen-Probe's response to this Request is made subject to and without waiver of the following Objections: Gen-Probe incorporates each of the foregoing General Objections into its response. Gen-Probe further objects to this Request on the grounds that it is overly broad and not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe also objects to the definition of "Related Patent" to the extent it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. *Gen-Probe's responses will limit the definition of "Related Patent" to non-pending domestic parent and foreign equivalent patents and patent applications for the asserted Process Patents.* Gen-Probe also objects to this Request on grounds that it calls for production of information protected by the attorney-client privilege, the work product doctrine, and/or other privileges and immunities. (Emphasis added)

A. BD's Statement of Reasons to Compel Discovery:

Each of the five asserted "Process Patents" claims priority to a single provisional patent application filed in 1998. BD's Request No. 12 and other similar requests seek documents concerning the prosecution of, and inventions claimed in, these "Related" patents and applications in the same family as the asserted Process Patents. Gen-Probe's improper responses limit its production to non-pending parent patents and applications (and foreign equivalents), in effect, just two additional issued patents (U.S. Pat. Nos. 6,890,742 and 6,335,166) of the 26 patents and applications in the U.S. family.

Documents concerning Gen-Probe's prosecution of related applications and the inventors' development of the alleged invention(s) claimed therein are central to BD's defenses under §§ 102, 103 and 112, inequitable conduct, claim construction and prosecution history estoppel. See, e.g. Advanced Cardiovascular Sys. v. Medtronic, 265 F.3d 1294, 1305 (Fed. Cir.

²⁶ Gen-Probe's objection and response to Request No. 12 is representative of other responses in which Gen-Probe limits its responses to documents concerning *non-pending domestic parent and foreign equivalent patents and patent applications for the asserted Process Patents*. These requests include Request Nos. 5, 7-9, 10-11, 14-15, 17, 132-133, and 135-136.

2001) ("The prosecution history of a related patent can be relevant if, for example, it addresses a limitation in common with the patent in suit."); Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999).²⁷ BD therefore requests an order compelling Gen-Probe to produce documents responsive to Request Nos. 5, 7-9, 10-12, 14-15, 17, 40, 132-133, and 135-136

B. Gen-Probe's Statement of Reasons for Objecting to Discovery:

BD's arguments concerning "Related Patents" are specious. As a result of the parties' meet-and-confer, Gen-Probe has *agreed* to produce the prosecution histories of the "Related Patents" under BD's definition of that term, (Long Decl. ¶ 9), in acknowledgement of BD's argument that those histories could bear on claim construction and any alleged prosecution history estoppel. However, BD is attempting to use a contrived dispute on one document request to obtain a blanket ruling on the relevance of "all documents" concerning all "Related Patents." The Court should reject that attempt.

For example, subsumed within BD's footnote argument that BD's Request No. 12 "is representative of other responses" is BD's request for "all documents concerning the decision to file" for a "Related Patent" (Ex. A., Request No. 9, at 11) and "all documents concerning any alleged unexpected results or advantages" of a "Related Patent" (Ex. A, Request No. 15, at 16). These requests, relating to patents *not* being asserted by Gen-Probe and not alleged to be invalid by BD, lack any relevance to any claim or defense in this case.

Finally, BD does not have a defense of "inequitable conduct" at issue in this case. BD's attempt to shoehorn a basis for its far-reaching "fishing expedition" discovery requests as part of its unsupported "unclean hands" defense is precisely the reason why Gen-Probe has asked the Court to strike that defense. (*See* Dkt. No. 38.) That motion remains pending, and BD has still not pleaded any "inequitable conduct" defense with the requisite particularity required under Fed. R. Civ. P. 9(b). *See Exergen Corp. v. Wal-Mart Stores*, 575 F.3d 1312, 1327 (2009).

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²⁷ Notably, Gen-Probe agreed to produce documents concerning all patents and applications "related" to the other asserted patents (Request Nos. 2, 6, 13, 40-42, 44-55, 57-58, 70, 83-84).

1 **C. BD's Reply to Gen-Probe's Statement of Reasons:**

2 Non-privileged documents concerning the prosecution of unasserted patents in the
3 asserted patent family contain information relevant to invalidity, claim construction, and other
4 issues pertaining to the asserted patents, including material that exists solely in Gen-Probe's
5 possession. Discussions between or commentary by Named Inventors concerning the
6 distinctions between the various patent applications are equally, if not more, relevant than
7 official file histories maintained by the Patent Office. Despite Gen-Probe's efforts to
8 characterize such requests as "fishing expeditions," BD has limited its requests to a known set of
9 patents and inventions that are related to the patents at issue in this case. Gen-Probe has not
10 demonstrated that a full response to this request would be unduly burdensome. *See supra* Part V.
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IX. **Gen-Probe's Refusal to Produce Non-Privileged Documents Concerning its Decision to File Patent Applications and its Decision to Develop the Products**

Request No. 51: All documents concerning the decision to file an application for a patent covering any invention claimed in the Cap Patents or Related Patents.

Response: Gen-Probe will produce non-privileged and responsive documents in its possession, custody, or control that can be identified after a reasonable search, to the extent such documents have not already been produced.

Gen-Probe's response to this Request is made subject to and without waiver of the following Objections: Gen-Probe incorporates each of the foregoing General Objections into its response. *Gen-Probe further objects to this Request on the grounds that it, including at least the phrase "concerning the decision to file," is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.* Gen-Probe further objects to the definition of "Related Patent" to the extent it is overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe's responses will limit the definition of "Related Patent" to non-pending domestic parent and foreign equivalent patents and patent applications for the asserted Cap Patents. Gen-Probe further objects to this Request on grounds that the burden or expense of the proposed discovery outweighs its likely benefit. Gen-Probe also objects to this Request on grounds that it calls for production of information protected by the attorney-client privilege, the work product doctrine, and/or other privileges and immunities. (Emphasis added).

Request No. 177: All documents concerning Gen-Probe's decision(s) to develop its TIGRIS Instrument and Gen-Probe's Penetrable Caps.

Response: Gen-Probe will produce non-privileged and responsive documents in its possession, custody, or control that can be identified after a reasonable search.

Gen-Probe's response to this Request is made subject to and without waiver of the following Objections: Gen-Probe incorporates each of the foregoing General Objections into its response. *Gen-Probe further objects to this Request on the grounds that it, including the phrase "decision(s) to develop," is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence.* Gen-Probe further objects to this Request on grounds that the burden or expense of the proposed discovery outweighs its likely benefit. Gen-Probe also objects to this Request on grounds that it calls for production of information protected by the attorney-client privilege, the work product doctrine, and/or other privileges and immunities. (Emphasis added).

A. **BD's Statement of Reasons to Compel Discovery:**

Gen-Probe informed BD during the parties' meet-and-confer that it refused to search for documents responsive to Request Nos. 51 and 177, based on its objections to the terms "decision to file" a patent application (Req. No. 51) and "decision to develop" the TIGRIS instrument or penetrable caps (Req. No. 177). These terms are not ambiguous. Responsive documents include

1 correspondence, email, memoranda, meeting notes, etc., analyzing or discussing the planned
2 course of action, potential outcomes, opportunities, costs, or revenues. The documents are
3 highly relevant to BD's defenses of patent invalidity and Gen-Probe's claims of non-obviousness
4 as well as any alleged damages. BD therefore requests that the Court overrule Gen-Probe's
5 objections to Request Nos. 51 and 177 and order Gen-Probe to produce responsive documents.
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7 **B. Gen-Probe's Statement of Reasons for Objecting to Discovery:**

8 As with many of BD's 196 requests, Request Nos. 51 and 177 are vague, overbroad and
9 cumulative, leaving Gen-Probe in doubt as to how to begin searching for responsive documents
10 (such as identifying keywords it could use to find responsive ESI). During the parties' meet-and-
11 confer on this issue, BD clarified "decisions to file" and "decisions to develop" to address
12 discussions on the pros and cons of filing an application for Gen-Probe's Penetrable Cap Patents,
13 and developing its TIGRIS instrument and penetrable caps. Based on BD's clarifications, Gen-
14 Probe agreed to conduct a reasonable search for such documents. Thus, no dispute remains.

15 **C. BD's Reply to Gen-Probe's Statement of Reasons:**

16 Based on Gen-Probe's representation in its response, BD agrees that no dispute remains.
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1 **X. Gen-Probe's Refusal to Search for Responsive Documents**

2 **Request No. 141:**²⁸ All documents concerning the Accused Products, including all documents
3 concerning any purchase, acquisition, investigation, examination, study, analysis and testing,
4 including any protocol or results, of any Accused Product by, for, or on behalf of Gen-Probe.

5 **Response:** Gen-Probe will produce non-privileged and responsive documents *in the possession*
6 *of any custodian whose files are searched in response to any other Request* that can be
7 identified after a reasonable search.

8 Gen-Probe's response to this Request is made subject to and without waiver of the following
9 Objections: Gen-Probe incorporates each of the foregoing General Objections into its response.
10 Gen-Probe further objects to this Request on the grounds that it is overly broad, vague and
11 ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of
12 admissible evidence. Gen-Probe also objects to this Request on grounds that it calls for
13 production of information protected by the attorney-client privilege, the work product doctrine,
14 and/or other privileges and immunities. (Emphasis added)

15 **A. BD's Statement of Reasons to Compel Discovery:**

16 In violation of its discovery obligations, Gen-Probe arbitrarily limits its response to BD's
17 Request No. 141 (and 138-140) to production of documents in the possession of individuals
18 whom Gen-Probe has identified as possessing documents responsive to other requests. BD
19 requests that the Court order Gen-Probe to conduct a reasonable search for documents responsive
20 to Requests Nos. 138-141, including in shared or common files not attributable to any one
21 custodian or files of individuals that Gen-Probe believes may contain responsive documents.

22 Documents concerning BD and the accused products are unquestionably relevant to Gen-
23 Probe's claims. To the extent Gen-Probe does possess "voluminous" files concerning BD or
24 BD's products, such information would be particularly relevant to BD's defenses, including
25 laches. In fact, Gen-Probe has no specific factual basis for its objections and limited response to
26 BD's requests. See Tourgeman v. Collins Financial Services, Inc., 2010 WL 2181416, *4 (S.D.
27 Cal., May 25, 2010) (Stormes, M.J.). For these reasons, BD requests that the Court order Gen-
28 Probe to conduct a reasonable search for and produce documents responsive to Request Nos.
138-141.

28 ²⁸ Gen-Probe's response to Request No. 137 is representative of its response to Request Nos.
138-140.

1 **B. Gen-Probe's Statement of Reasons for Objecting to Discovery:**

2 This dispute once again boils down to what may be considered a "reasonable search" to
 3 BD's grossly overbroad discovery requests for "all documents." In addition to Request 141,
 4 BD's Request No. 138, which seeks "All documents concerning BD," (Ex. A at 99), further
 5 illustrates the far-reaching and excessively burdensome nature of BD's Request Nos. 137-141.
 6 BD now moves the Court to order Gen-Probe to conduct an unreasonable search for documents
 7 responsive to those requests including in shared or common files not attributable to any one
 8 custodian or in files of individuals that Gen-Probe believes may contain responsive documents.

9 BD is talking out of both sides of its mouth. During the parties' meet-and-confer efforts,
 10 BD clarified that:

11 BD is not suggesting that, in response to these requests, Gen-Probe
 12 must conduct unreasonable searches for any piece of paper that
 refers in passing to BD.

13 (Long Decl. ¶ 7). Thus, BD has acknowledged that its requests, as drafted, are unreasonable and
 14 overbroad. Yet BD has not amended its requests and is still pursuing its quest for "all documents
 15 concerning the Accused Products" and "all documents concerning BD." Especially in view of
 16 BD's concession, Gen-Probe's approach – to search for "responsive documents in the possession
 17 of any custodian whose files are searched in response to any other Request that can be identified
 18 after a reasonable search" – is the only reasonable approach to responding to these requests.
 19 Gen-Probe's other responses to BD's 196 document requests make clear, for example, that Gen-
 20 Probe will search the files of the inventors of the asserted patents and those that materially
 21 assisted them, other key technical and patent personnel, and Gen-Probe's marketing and sales
 22 managers. That search will include shared and "department" files. And, as part of Gen-Probe's
 23 proposed protocol for searching its ESI, Gen-Probe disclosed to BD that it proposes to search the
 24 files of sixteen different individuals for responsive information. (*Id.* ¶¶ 11-12, Ex. 4.) BD's own
 25 proposed ESI search protocol takes the same approach, naming twenty-eight individuals whose
 26 files it proposes to search. (*Id.* ¶ 13, Ex. 5.) In light of BD's own proposed search methods for
 27 both ESI and hardcopy documents, it is disingenuous for BD to complain about Gen-Probe's
 28 approach to searching for "all documents concerning" BD or its Accused Products.

1 **C. BD's Reply to Gen-Probe's Statement of Reasons:**

2 Gen-Probe's objections to requests seeking "all" documents are once again disingenuous.
3 BD requests that, to the extent Gen-Probe identifies an individual, other than the 16 people
4 named in its proposed ESI protocol, in possession of responsive ESI or documents, such
5 documents must be produced. Gen-Probe cannot ignore responsive files simply because they
6 exist in shared files or because the files' custodians do not happen to possess documents
7 responsive to any other request. For these reasons, and because Gen-Probe does not assert any
8 undue burden or prejudice, Gen-Probe should be compelled to produce responsive materials.
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XI. Gen-Probe's Refusal to Produce Documents Based on the "Right to Privacy" in the California State Constitution (Article I, Section I)

Request No. 108:²⁹ All documents concerning agreements between Named Inventors and Gen-Probe.

Response: Gen-Probe will produce agreements *relating to intellectual property rights* in its possession, custody, or control that can be identified after a reasonable search.

Gen-Probe's response to this Request is made subject to and without waiver of the following Objections: Gen-Probe incorporates each of the foregoing General Objections into its response. Gen-Probe further objects to this Request on the grounds that it is overly broad, vague and ambiguous, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence. Gen-Probe also objects to this Request on grounds that it calls for production of information protected by the attorney-client privilege, the work product doctrine, and/or other privileges and immunities. Gen-Probe further objects to this Request *on grounds that it calls for production of information protected by federal and state privacy laws.* (Emphases added)

A. BD's Statement of Reasons to Compel Discovery:

During the meet and confer, Gen-Probe stated that the sole basis for its objections to Request No. 108 and similar requests was Article 1, section 1 of the California State Constitution. Although Article 1, section 1 does grant a right to privacy, it is not an absolute one where, as here, the Court has entered a protective order. *See, e.g. Moskowitz v. Superior Court*, 137 Cal. App. 3d 313, 316, 319 (Cal. Ct. App. 1982); *Hecht, Solberg, Robinson, Goldberg & Bagley v. Superior Court*, 137 Cal. App. 4th 579, 599 (Cal. Ct. App. 2006). The requested documents are relevant to, for example, the payments by Gen-Probe to the named inventors, including any contingent or ongoing compensation and the potential bias or credibility of Gen-Probe's witnesses. Since the privacy rights "relied" on by Gen-Probe do not outweigh BD's need for these highly relevant documents, BD requests that the Court order Gen-Probe to produce documents responsive to Request Nos. 108-110, 114, and 162.

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²⁹ Gen-Probe's response to Request No. 108 is representative of other responses in which Gen-Probe refuses to produce responsive documents on the basis of state and federal privacy laws including Nos. 109-110 (agreements between Gen-Probe, Named Inventors, and/or entities affiliated with Named Inventors), No. 114 (money paid by Gen-Probe or their employers to the Named Inventors), and No. 162 (personnel files for any person identified in Gen-Probe's initial disclosures or answers to interrogatories, or designated as a 30(b)(6) witness for Gen-Probe).

1 **B. Gen-Probe's Statement of Reasons for Objecting to Discovery:**

2 The right to privacy is not the "sole basis" for Gen-Probe's objections to BD's Request
3 Nos. 108, 109, 110, 114 and 162 that seek, for example, the personnel files for any person
4 identified in Gen-Probe's initial disclosures, etc. (Request No. 162), but it is a substantial basis
5 on which to deny BD's motion on both substantive and procedural grounds.

6 Substantively, these requests violate the provisions of the California Constitution that
7 guarantee individuals an inalienable right to privacy. CAL. CONST., ART. I § 1. Federal and state
8 case law establishes that this right limits permissible discovery. *See, e.g., Davis v. Leal*, 43 F.
9 Supp. 2d 1102, 1110-12 (E.D. Cal. 1999). Courts are required to conduct a balancing test,
10 weighing "the needs of the litigation [against] the sensitivity of the information/records sought."
11 *Id.* at 1110. Private financial information is *presumptively* privileged. *Id.* at 1111. "Where there
12 is no doubt that the information requested implicates traditional notions of what is private
13 information... the burden is on the requesting party to demonstrate that the information is
14 directly relevant to the case, and that the information needs of the case outweigh the need for
15 non-disclosure." *Id.* BD has done nothing to meet that burden.

16 BD's requests are not even limited to financial information but seek a broad and invasive
17 scope of personal documents including the entire personnel files for any person identified in
18 Gen-Probe's initial disclosures or interrogatory answers, or designated as a 30(b)(6) witness. BD
19 made no attempt to limit its requests, but instead argues for the discovery because it might
20 somehow be useful to show the inventors' or witnesses' bias. This "fishing expedition" rationale
21 is weak and does not warrant trampling the privacy rights of individuals. At this stage, BD has
22 not satisfied the requisite showing to overcome the privacy rights of those individuals.

23 Furthermore, BD has failed to satisfy reasonable procedural steps necessary before the
24 Court can order disclosure of private financial, personal and employment information to BD.
25 For example, BD has failed to provide notice to any of the individuals whose records are
26 implicated, effectively denying them the opportunity to defend their rights. *See, e.g., Sehlmeier*
27 *v. Department of General Svcs.*, 17 Cal. App. 4th 1072, 1080-81 (1993) (requiring notice to third
28

1 party in context of subpoena for third party personal records). Finally, BD's contention that the
 2 existing protective order automatically obviates the privacy rights of these third parties has been
 3 rejected by the courts. *See Davis v. Leal*, 43 F. Supp. 2d at 1111.

4 Gen-Probe has agreed to produce the only responsive agreements for which there is any
 5 arguable substantive relevance – the inventors' agreements relating to their intellectual property
 6 rights. Any more invasive discovery is unwarranted at this stage.

7
 8 **C. BD's Reply to Gen-Probe's Statement of Reasons:**

9 Evidence of bias is directly relevant to each issue to which a witness testifies. Gen-
 10 Probe asserts that a court has "rejected" the sufficiency of protective orders to preserve the
 11 privacy of third parties. However, even the case cited by Gen-Probe in support of this
 12 proposition recognizes that such orders "may go some distance in ameliorating any untoward
 13 privacy invasion." *Davis v. Lear*, 43 F. Supp. 1102, 1111 (E.D. Cal. 1999). Gen-Probe's
 14 suggestion that BD has somehow skirted its procedural duties to third parties by failing to issue
 15 notice that their personnel records are sought is similarly disingenuous. The case cited by Gen-
 16 Probe dealt with subpoenas, which carry more immediate consequences for the resisting party.
 17 Moreover, Gen-Probe failed to acknowledge that any duty to notify third parties of potential
 18 privacy violations could belong to Gen-Probe rather than BD. In *Valley Bank of Nevada v.*
 19 *Superior Court*, 15 Cal. 3d 652, (Cal. App. 1975), it was the party *resisting* discovery that had a
 20 notice requirement; in this case, Gen-Probe, not BD.

21 Any privacy rights implicated by BD's request for documents highly relevant to the
 22 credibility of Gen-Probe's witnesses, among other topics, are adequately protected by the
 23 stringent protective order in place in this case. Therefore, the Court should compel the
 24 production of documents responsive to this request.

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Respectfully submitted,

Dated: July 21, 2010

FOLEY HOAG LLP

By: s/Brian Carroll

Attorneys for Defendant and
Counterclaimant BECTON, DICKINSON
AND COMPANY

Dated: July 21, 2010

LATHAM & WATKINS LLP

By: s/Alexander Long

Attorneys for Plaintiff and Counterdefendant
GEN-PROBE INCORPORATED

**CERTIFICATION OF COMPLIANCE WITH MEET AND CONFER
REQUIREMENT**

Plaintiff Gen-Probe Incorporated ("Gen-Probe") and Defendant Becton, Dickinson and Company ("BD") hereby certify that they have complied with the meet and confer requirement of L.R. 26.1(a).

Dated: July 21, 2010

LATHAM & WATKINS LLP

By: s/Alexander Long

Attorneys for Plaintiff and Counterdefendant
GEN-PROBE INCORPORATED

Dated: July 21, 2010

FOLEY HOAG LLP

By: s/Brian Carroll

Attorneys for Defendant and
Counterclaimant BECTON, DICKINSON
AND COMPANY

CERTIFICATE OF SERVICE

I hereby certify that on July 21, 2010, I caused the **JOINT MOTION FOR DETERMINATION OF DISCOVERY FOURTH DISPUTE** to be electronically filed with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following person(s):

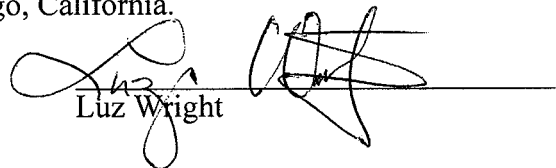
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I certify and declare under penalty of perjury under the laws of the State of California that I am employed in the office of a member of the bar of this Court at whose direction the service was made, and that the forgoing is true and correct.

Executed on July 21, 2010, at San Diego, California.


Luz Wright

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